



# Federal Preemption of State Liability Claims under the FDCA

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## **Federal Preemption of State Liability Claims Under the FDCA**

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## **Federal Preemption of State Liability Claims Under the FDCA**

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**Abstract:** Although the FDA has a history of working in cooperation with state governments, in recent years the Agency has increasingly sought to pre-empt certain state law rights of action and tort claims. Parts II and III of this paper will provide an brief overview of federal preemption law and move on to an account of how the FDA developed its strong pro-preemption stance. Next, Part IV will explore arguments both for and against federal preemption of certain state law claims. Part V discusses possible judicial reactions to the FDA's preemption position. Finally, Part VI proposes that courts should accept the Agency's preemption efforts are the most effective approach for the agency to fulfill its Mission.

**“To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.”**

## **–FDA Mission Statement**

### **I.**

#### **Introduction**

Every civilization has had some form of regulatory impact on the substances ingested by its citizenry.<sup>1</sup> From the first Sumerian laws prohibiting watered-down ale<sup>2</sup> to medieval England’s *Assize of Bread and Ale*,<sup>3</sup> this form of regulation has always been concerned with protecting people from economic fraud as well as from ingesting impure and potentially harmful substances.

In the United States, modern food and drug regulation has a largely reactionary history.<sup>4</sup> Although the groundwork had been laid in the 1800’s to establish a federal agency protecting Americans from ingesting adulterated substances, Congress did not take action until 1906 when Upton Sinclair published “The Jungle.”

<sup>5</sup> Sinclair’s novel, describing the horrific working conditions in Chicago’s meatpacking facilities, shocked U.S. consumers and resulted in a Congressional investigation.<sup>6</sup> When Sinclair’s allegations were found to

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<sup>1</sup>Peter Barton Hutt, Food and Drug Law Course Lecture, Harvard Law School (Jan. 3, 2006).

<sup>2</sup>*Id.* (oldest proven records refer to Sumerian rules about ale and are over 6,000 years old). *See also* [http://en.wikipedia.org/wiki/History\\_of\\_beer](http://en.wikipedia.org/wiki/History_of_beer) (contains a photo of the Alulu Tablet, a receipt for “best beer” from 2050 BC).

<sup>3</sup>England’s ASSIZE OF BREAD AND ALE is the earliest English legislation regulating the price of bread. The Assize dates from 1226 and fixed the size, weight, and price of loaves of bread at <http://www.law.harvard.edu/library/collections/special/publications/food/food1.php>.

<sup>4</sup>Medical disasters are often the impetus for Congress to present a public health bill to a president. James H. Young, *The Long Struggle for the 1906 Law*, FDA Consumer (June 1981). The FDA account of its history stated that Sinclair’s graphic depiction of the meat packing industry was the “final precipitating force behind both a meat inspection law and a comprehensive food and drug law.” John P. Swann, *History of the FDA*, adapted from a *Historical Guide to the U.S. Government* (George Kuran ed., 1998) at <http://www.cfsan.fda.gov/~lrd/history2.html>.

<sup>5</sup>Young, *supra* note 4.

<sup>6</sup>UPTON SINCLAIR, *THE JUNGLE*, (RANDOM HOUSE 2002) (1906). Sinclair described the filthy conditions in a meat packing plant as follows: “There was never the least attention paid to what was cut up for sausage; there would come all the way back from Europe old sausage that had been rejected, and that was moldy and white – it would be dosed with borax and glycerin,

be true, the ensuing public outrage prompted Congress to enact the Food and Drug Act of 1906, creating a federal agency to protect consumers from the dangers posed by unregulated substances.<sup>7</sup> This agency ultimately became known as the Food and Drug Administration (“FDA”).<sup>8</sup> The creation of a federal public health agency marked a dramatic shift in federal policy because up until this point, states had exercised the principal control over the regulation of public health and medicine—although this legislation varied significantly from state to state.<sup>9</sup> In fact, prior to the 1906 Act, Congress had only passed one other law that dealt with the regulation of consumer protection.<sup>10</sup>

In 1938, Congress replaced the original act with the Food, Drug, and Cosmetic Act (“FDCA”), which included a premarket approval process for pharmaceutical drugs.<sup>11</sup> The FDCA granted the FDA enormous regulatory control over the daily lives of United States citizens. The FDA as we now know it grew from a single chemist in the U.S. Department of Agriculture in 1862 to a staff of approximately 9,100 employees and a budget of \$1.294 billion in 2001.<sup>12</sup> In stark contrast to its humble beginnings, the FDA’s jurisdiction currently encompasses most food products (other than meat and poultry), human and animal drugs, biologics, animal feed and other livestock products, cosmetics, radiation-emitting products, and most recently bioterrorism

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and dumped into the hoppers, and made over again for home consumption....There were things that went into the sausage in comparison with which a poisoned rat was a tidbit. (BLOODWORTH, WILLIAM A., *THE JUNGLE*: UPTON SINCLAIR. BOSTON: TWAYNE PUBLISHERS AT 134-5 (1977). Although Sinclair’s novel caused a public uproar that ultimately led to the passage of the Meat Inspection Act in 1906 and the Food and Drug Act of 1906, his objective in writing *THE JUNGLE* was not to inspire public health reforms. Rather, Sinclair hoped to promote Socialism by demonstrating the inhumane working conditions that Capitalism created. Sinclair later lamented, “I aimed at the public’s heart, and by accident hit it in the stomach.” *Id.* at 84. See also Young, *supra* note 4.

<sup>7</sup>Federal Food and Drug Act of 1906, Ch. 3915, 34 State. 768.

<sup>8</sup>The FDA was originally called the Division of Chemistry. In 1927, the name was changed to the Food, Drug, and Insecticide Administration, and in 1930, the Agency adopted its current name. Young, *supra* note 4.

<sup>9</sup>*Id.* See also Sasha B. Rieders “State Law Tort Claims and the FDA: Proposing A Consumer-Oriented Prescription in Medical Device Cases” 25 Cardozo L. Rev. 1159, n4 (Feb. 2004) (The 1906 Act marked the federal government’s first significant legislation in the public health domain); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (“Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are “primarily, and historically... matter[s] of local concern,” the “States traditionally have had great latitude under their police powers to legislate as to the protections of the lives, limbs, health, comfort, and quiet of all persons.” (quoting *Hillsborough County v. Automated Medical Laboratories, Inc.* 471 U.S. 707, 719 (1985)).

<sup>10</sup>Congress had previously passed the Vaccine Act of 1813. Swann, *supra* note 4.

<sup>11</sup>Pub. L. No. 75-717, 52 Stat. 1040 (1938). See also *Lohr*, 518 U.S. at 474 (discussing the history of the FDCA).

<sup>12</sup>Swan, *supra* note 4.

agents.<sup>13</sup> According to its website, the FDA oversees items accounting for 25 cents of every dollar spent by consumers.<sup>14</sup> Moreover, the FDA monitors the manufacture, import, transport, storage, and sale of about \$1 trillion worth of products annually at a cost to taxpayers of about \$3 per person.<sup>15</sup> Although the FDA has a history of working in cooperation with state governments, in recent years the Agency has increasingly sought to pre-empt certain state law rights of action and tort claims. Parts II and III of this paper will provide an brief overview of federal preemption law and move on to an account of how the FDA developed its strong pro-preemption stance. Next, Part IV will explore arguments both for and against federal preemption of certain state law claims. Part V discusses possible judicial reactions to the FDA’s preemption position. Finally, Part VI proposes that courts should accept the Agency’s preemption efforts are the most effective approach for the agency to fulfill its Mission.

## II.

### Federal Preemption of State Legislation Can Be Express or Implied

Historically, the states have exercised their police powers to regulate the protection of citizens’ health, safety, and welfare.<sup>16</sup> However, under the Supremacy Clause of the United States Constitution, the laws of the United States are “... the supreme Law of the Land... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”<sup>17</sup> Accordingly, when a federal statute or regulation conflicts with a state

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<sup>13</sup>[www.fda.gov](http://www.fda.gov). See also Wallace F Janssen, FDA Historian, *The Story of the Laws Behind the Labels*. (Throughout its 100-year history, the food and drug statute has changed from being primarily a criminal statute to a law that is now dominantly preventive through informative regulations and pre-market controls) at <http://www.cfsan.fda.gov/~lrd/history1.html>

<sup>14</sup>Swan, *supra* note 4.

<sup>15</sup>*Id.*

<sup>16</sup>Michael Carrier, “Federal Preemption of Common Law Tort Awards by the Federal Food, Drug, and Cosmetic Act,” 51 Food & Drug L.J. 509 (1998) *citing* *Florida Lime & Avocado Growers, Inc. v. Paul* 373 U.S. 132, 144 (1963) (food regulation is “an exercise of the ‘historic police powers of the states’”); and *Hillsborough* 471 U.S. at 719 (county ordinance is permissible given the traditional presumption against federal preemption in the areas of health and safety).

<sup>17</sup>U.S. Const. Art. VI, cl. 2.

law, the federal law preempts the state law.<sup>18</sup> Federal preemption of state law can happen in a number of ways. In some instances, Congress will explicitly proclaim that federal law precludes state action. This is known as express preemption.<sup>19</sup> In other instances, Congress has not expressly stated that state action is preempted, but preemption is implied because the state action would either conflict with federal action (conflict preemption) or because the federal scheme “occupies the field” leaving no room for state action (field preemption).<sup>20</sup>

Although Congress granted the FDA broad jurisdiction to promulgate rules and regulations, prescription pharmaceuticals are not subject to an express preemption provision under the FDCA.<sup>21</sup> Accordingly, courts have been reluctant to find that federal law impliedly preempts state laws in the public safety arena “unless that was the clear and manifest purpose of Congress.”<sup>22</sup> Increasingly, drug manufacturers have asked the courts to apply the doctrine of implied preemption in the context of pharmaceutical product liability cases.<sup>23</sup>

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<sup>18</sup>*McCulloch v. Maryland*, 17 U.S. 316, 427 (1819). *See also Caraker v. Sandoz Pharm. Corp.* 172 F.Supp 2d 1018, 1030 (S.D. Ill. 2001) (“[The Supremacy Clause] gave birth to the preemption doctrine, under which federal statutes *and agency regulations* may preempt state law.” emphasis added.). Note that both federal regulations and federal statutes can preempt state law. *Hillsborough* 471, U.S. at 713.

<sup>19</sup>Perhaps on of the most famous cases in the food and drug law area was the federal regulation of cigarette labels. *Cipollone v. Liggett Group Inc.*, 505 U.S. 504 (1992).

<sup>20</sup>Memorandum from Dechert, LLP “FDA Supports Implied Preemption of Certain Warning Claims in Product Liability Litigation Involving Prescription Drugs and Biologics” (Feb. 2006) *available at* [www.dechert.com/productliability](http://www.dechert.com/productliability), *citing* *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (Supreme Court held that federal law preempted a state-law design defect suit against a car manufacturer for failing to install air bags. Court found that the Department of Transportation had considered and rejected a regulation that would have made air bags mandatory in all cars. Therefore, making the manufacturer liable under state law posed “an obstacle to” the DOT’s deliberate policy decision not to require airbags).

<sup>21</sup>Pub. L. No. 87-781 § 202, 76 Stat. 780, 793 (1962) (codified at 21 U.S.C. § 321 (2000)) (“Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetics Act shall be construed as invalidating any provision of State law...unless there is a direct and positive conflict between such amendments and such provisions of State law.” *Compare* with medical devices, which are governed by the Medical Device Amendment to the FDCA. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified 21 U.S.C. § 355 (2000)). The MDA contains an express preemption clause although courts are divided about how to interpret this clause. Michael C. Levy & Gregory J. Wartman, “Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA’s Influence on Federal Preemption of Class III M” (noting that although a majority of courts have found federal preemption with respect to MDA devices, the Tenth and Eleventh Circuits have held that the MDA does not have a preemption effect on state common law tort claims).

<sup>22</sup>*Carrier*, *supra* note 16 at 509, *citing* *Rice v. Santa Fe Elevator Corp.* 331 U.S. 218, 230 (1947). *See* *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) (quoting, *Retail Clerks Int’l Ass’n v. Sochermerhorn*, 375 U.S. 96, 103 (1963) (“the purpose of Congress is the ultimate touchstone” in conducting a preemption analysis).

<sup>23</sup>*See, e.g.,* *Feldman v. Lederlee Laboratories*, 125 N.J. 117 (1991) (New Jersey Supreme Court held that the FDCA did not preempt plaintiff’s common law claims against manufacturer of cold medication for failure to warn about adverse consequences of drug). *R.F. and R.F. v. Abbott Laboratories* 162 N.J. 596 (2000) (New Jersey Supreme Court concluded that the FDCA preempted plaintiff’s common law claims against manufacturer of a device used to screen blood for HIV virus because it was impossible to comply with both state and federal requirements. The FDA had specifically rejected additional warnings on the

A recent move by FDA to expressly preempt certain state product liability laws comes amid a flurry of high-profile state and federal pharmaceutical liability cases and has caused a stir among consumer rights advocates and plaintiff's attorneys.

### III.

#### FDA Supports Preemption of Certain Warning Claims in Product Liability Litigation Involving Prescription Drugs and Biological Products

On January 18, 2006, the FDA issued a major policy statement regarding the preemptive effect of its prescription drug labeling determinations over state-law liability claims.<sup>24</sup> While the new labeling guidelines were widely applauded, trial lawyers and members of Congress quickly attacked the claim of federal preemption as another effort by the Bush administration to limit the public's ability to bring and win lawsuits.<sup>25</sup> The source of the preemption statement is found in the preamble to "Requirements on Content and Format of Labeling Human Prescription Drug and Biological Products" which revises the previous requirements on the content and format of the approved labeling for prescription drugs and biologics.<sup>26</sup> The relevant language in the preamble asserts that the FDA's decisions on drug labeling matters will take precedence over conflicting state-law requirements, whether imposed through legislation, regulations, or product liability law.<sup>27</sup>

#### A.

package). Hurly v. American Cyanamid 863 F.2d 1173 (5th Cir. 1998) (plaintiff alleged that manufacture failed to warn about specific effects of a vaccine. District Court and the Court of Appeals for the Fifth Circuit held that federal vaccine regulations enacted pursuant to the FDCA implicitly preempted any state law defective design or inadequate warning claims).

<sup>24</sup>This is the first significant change in the FDA's drug labeling requirements in more than 25 years.

<sup>25</sup>*See, e.g.*, Letter from Senator Kenney & Senator Dodd to Secretary of Health and Human Services Michael Leavitt (Feb. 23, 2006).

<sup>26</sup>21. C.F.R. Parts 201, 214, and 601. The final rule is highly detailed, comprising nearly 300 pages in printed form. The codified version of the rule does not address preemption. However, the preamble does so in both the FDA's responses to comments on the product liability implications of the new "Highlights" requirements and the discussion of Executive Order 13132.

<sup>27</sup>*Id.*



## History of the Revised Labeling Rule

According to the Journal of the American Medical Association, adverse drug reactions constitute the fourth highest cause of death in America and an astonishing 300,000 preventable adverse drug events occur every year.<sup>28</sup> Moreover, there is a growing realization that physicians and consumers are not reading (or understanding) the labels and package inserts for prescription drugs.<sup>29</sup> Richard H. Carmona, the U.S. Surgeon General summed up the problem when he noted, “Americans are overwhelmed with the complexity of health information. We have hit a point of information overload and the public health message is being diluted.... This problem is compounded by prescription medication information that reads more like legal disclaimers than useful or actionable health information.”<sup>30</sup> In response to this problem, FDA proposed a new labeling rule designed to make labels and package inserts easier to understand for physicians and patients.<sup>31</sup> One of the key changes was a proposal to require drug manufacturers to include a “Highlights” section on the label that will provide “... immediate access [for physicians] to the most important prescribing information about benefits and risks.”<sup>32</sup>

When FDA first proposed revising the rule for format and content requirements of prescription drug labels,

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<sup>28</sup>Pomeranz J.Lazarou, “Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies,” Journal of the American Medical Association; 279: 1200 - 1205 (Apr 15, 1998) (adverse drug reactions cause the death, hospitalization, or serious injury of more than 2 million people in the United States each year, including more than 100,000 fatalities).

<sup>29</sup>Studies show that fewer than one in 10 physicians routinely read drug labels, which provide the most complete information about a drug’s dangers and uses. Moreover, when they do read labels, studies show, doctors learn little. Major changes to drug labels have in the past done little to stop dangerous prescribing habits by physicians. Gardiner Harris, “New Drug Label Rule Is Intended to Reduce Medical Errors” New York Times (Jan. 19, 2006) [hereinafter “New Drug Label Rule”].

<sup>30</sup>Press Release, Food and Drug Administration “FDA Announces New Prescription Drug Information Format to Improve Patient Safety” (Jan. 18, 2006).

<sup>31</sup>“Each year, approximately 300,000 preventable adverse events occur... many as a result of confusing medical information. Research shows that prioritizing the warning information has a greater impact on reducing such events....By making these changes, FDA is seeking to reduce the complexity of information on prescription drug labels, making them more useful for physicians and their patients.” *Id.*

<sup>32</sup>Other significant changes include a “...*Table of Contents* for easy reference to detailed safety and efficacy information[; t]he date of initial product approval (making it easier to determine how long a product has been on the market[; and a] toll-free number and internet site reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.” *Id.*

it published a Notice of Proposed Rulemaking (NPRM) in December 2000.<sup>33</sup> In compliance with Executive Order 13132, FDA conducted an analysis of the proposed rule to determine whether it contained any policies that had federalism implications or that would preempt state law.<sup>34</sup> FDA determined that there were no federalism implications and specifically stated, “this proposed rule does not preempt State law. Accordingly, the FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.”<sup>35</sup>

When it issued the NPRM, FDA specifically requested comment on product liability issues and asked if requiring manufacturers to include a “Highlights” section in labeling had “a significant effect on manufacturers’ product liability concerns.”<sup>36</sup> During the public comment period, numerous stakeholders submitted comments in response to the NPRM. While most of the comments supported the proposed rule, a few also urged the Agency to include a clear statement that FDA labeling requirements preempt inconsistent requirements under state law.<sup>37</sup> Although the NPRM generated significant interest in the health care and drug manufacturing industries, FDA did not take any action on the NPRM until January 2006 when it published the final rule in the Federal Register.<sup>38</sup> To the dismay of many consumer rights advocates and plaintiff’s attorneys,<sup>39</sup> the preamble to the final rule contained language preempting certain types of state-law tort litigation.<sup>40</sup> Indeed, the Agency states that preemption includes both claims against manufacturers as well

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<sup>33</sup>65 Fed. Reg. 81082 (December 22, 2000).

<sup>34</sup>E.O. 13132 sec. 4(d).

<sup>35</sup>65 Fed. Reg. at 81103.

<sup>36</sup>71 Fed. Reg. 3922 (January 24, 2006).

<sup>37</sup>In comments, some manufacturers expressed concerns that, by highlighting selected information from the FPI to the exclusion of information not highlighted, they make themselves more vulnerable to product liability claims. Some of these comments also stated that the Highlights limitation statement, which states that Highlights does not contain all the information needed to prescribe a drug safely and effectively and that practitioners should also refer to the FPI, would not constitute an adequate legal defense in a case alleging failure to provide adequate warning of a drug’s risks.” 71 Fed. Reg. at 3933; *see also* Bradshaw Says FDA Preempts State Tort Laws On OTC Drugs, FDA Week, Feb. 3, 2006 (quoting FDA Chief Counsel Sheldon Bradshaw as saying “Drug companies worried that they would be sued for following the regulation and leaving out some of the rarer or less dangerous side effects in this section so FDA included the big about preemption in the preamble.”).

<sup>38</sup>71 Fed. Reg. at 3922.

<sup>39</sup>*See, e.g.*, Press Release, American Trial Lawyers of America “FDA Uses Back Door to Issue New Rule Protecting Negligent Drug Companies: Rule Could Affect Majority of Drug Safety Cases.” (Jan. 18, 2006) at <http://www.atla.org/pressroom/PressReleases/2006/january18.aspx>.

<sup>40</sup>The FDA says that *at least* six types of “claims would be preempted by its regulation of prescription drug labeling: (1)

as against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling.<sup>41</sup>

B.

Inserting The Preemption Provision in the Revised Labeling Rule Reinforces FDA's  
use of Amicus Curiae Briefs to Persuade Courts to allow Federal Preemption of Certain State-  
Law Claims

FDA's position that state-law failure to warn claims are impliedly preempted because they conflict with its drug labeling regulations is not new. Prior to the publication of the new labeling rule, the Agency's position had been set forth in a number of *amicus curiae* briefs filed by the agency in recent years. Although FDA is an independent governmental body, its latest efforts to provide drug and device manufacturers with greater preemption protection can be partly attributed to politics.<sup>42</sup> In the past, FDA was relatively uninvolved in products liability litigation.<sup>43</sup> However, under the current Presidential Administration, FDA has advocated

claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling... ; (2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with the FDA draft guidance regarding the 'brief summary' in direct-to-consumer advertising; (3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in the rule...; (4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time a plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn); (5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and (6) claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's labeling (unless FDA has made a finding that the sponsor withheld material information relating to the statement).” 71. Fed. Reg. at 3936.

<sup>41</sup>*Id.*

<sup>42</sup>The NPRM was published during the final days of the Clinton administration whereas the rule was finalized during the Administration of George W. Bush. *See also*, Levy, *supra* note 21 at 495 (asserts that the Agency's efforts to allow for preemption of state tort matters began when President George W. Bush took office in 2000).

<sup>43</sup>Wilfred P. Coronato & Stephen Lanza, American Law Institute – American Bar Association Continuing Legal Education, Product Liability: Pharmaceutical and Medical Device Issues, “The Fracture that Will Not Heal: The Landscape of Federal Preemption in The Fields of Medical Devices, Prescription and Over-the-Counter D [Hereinafter “ALI-ABA] (The FDA's involvement in pharmaceutical cases is a relatively new development) *citing* Correy E. Stephenson, FDA involvement in Private Litigation: Harmful to Consumers, Or Good Policy?, *Lawyers Weekly USA* (Oct. 11, 2004) at <http://www.lawyersweekklyusa.com/reprints/mbrm.htm> (“Despite relatively limited intervention in the past, the FDA has filed numerous briefs and statements of interest in cases over the past three years. In fact, the FDA's chief counsel, Daniel Troy, has gone so far as to ask defense attorneys to notify the agency if they want it to lend support in their cases.”).

in favor of preemption in a number of *amicus curiae* briefs. One scholar described the Agency's *amicus curiae* briefs as an effort "to reinterpret its own regulations and reform product liability without formal rulemaking."<sup>44</sup>

Part of the reason that FDA has been so aggressive in filing *amicus curiae* briefs is because courts have generally not been open to preemption claims in prescription drug cases.<sup>45</sup> Congress' decision not to include a preemption clause in the pharmaceutical drug portion of the FDCA has led some commentators and courts to conclude "... unless Congress expressly preempts State and local labeling and warning requirements, they should never be preempted."<sup>46</sup> Nevertheless, FDA's *amicus curiae* efforts are a valid use of the authority granted to the agency and courts have cited their reliance on and deference to the expertise of an agency regarding matters the agency regulates.<sup>47</sup>

One of FDA's most influential *amicus* briefs was filed with the Court of Appeals for the Ninth Circuit in *Motus v. Pfizer*. In this case, the plaintiff filed suit against Pfizer for failing to warn her decedent of the alleged relationship between Zoloft and suicide.<sup>48</sup> Pfizer argued that federal law preempted the plaintiff's

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<sup>44</sup>Levy, *supra* note 21 at 505.

<sup>45</sup>ALI-ABA, *supra* note 42 at 384, *citing* Caraker 172 F.Supp. at 1037 ("Drug manufacturers have endlessly attempted to argue for preemption on the basis that the federal regulation of drug labels and package inserts would be undermined if state law imposed greater warning duties... on drug manufacturers that supplemented the warning label on the approved drug, but courts have generally still found no preemption."); *see also* Ohler v. Purdue Pharm, No. CIV.A 01-3061, 2002 WLA 88945 at 13 (observing that preemption jurisprudence with respect to prescription drug warnings has indicated no intent to preempt state law claims).

<sup>46</sup>ALI-ABA, *supra* note 42 at 383 *citing* Ohler, 2002 WL 88945 at 12; *see also* Consumer Justice Center v. Olympian Labs, 99 Cal. App. 4th 105 (June 2002) ("As far as the [FDCA] is concerned, it would be more accurate to say that the Act evidences, far from implied preemption, an instance of implied non-preemption. Congress wrote a specific preemption provision for medical devices in the [FDCA]. (21 U.S.C. § 360k(a).) The obvious implication is that no preemption was intended for other items covered by the Act.").

<sup>47</sup>Levy, *supra* note 21 at 507 ("When a statute speaks clearly to the issue at hand, courts 'must give effect to the unambiguously expressed intent of Congress,' but when the statute 'is silent or ambiguous,' courts must defer to a reasonable construction by the agency charged with its implementation." *Barnhard v. Thomas* 540 U.S. 20, 124 S. Ct. 376, 380 (2003) (quoting *Chevron U.S.A. Inc. v. Natural Res. Defense Council, Inc.* 467 U.S. 837, 843, 104 S.Ct. 2778 (1984); *Houston Police Officers' Union v. City of Houston, Tex.*, 330 F.3d 298, 302-03 (5th Cir. 2003) (noting that the appellant "fortified" its interpretation of a statute by arguing that it is advocated by the Department of Labor in an *amicus curiae* brief, as well as certain regulations and an opinion letter). The Court does not accord *Chevron* deference to the *amicus curiae* brief, as it is unclear whether the "pronouncement [ ] [is] sufficiently authoritative to merit *Chevron* deference." *Houston Police Officers Union*, 330 F.3d at 305. (The Court does however, place weight, though not dispositive weight, on the agency's view as expressed in the *amicus curiae* brief.). *Id.*

<sup>48</sup>*Motus v. Pfizer, Inc.* 127 F. Supp. 2d 1085, 1087 (C.D. Cal. 2000).

claim that an additional suicide warning should have been included in the package insert because it would frustrate congressional purposes.<sup>49</sup> Pfizer's preemption claim failed to persuade the district court and the case was appealed to the Court of Appeals for the Ninth Circuit.<sup>50</sup> Hoping to influence the court's decision, FDA filed an *amicus curiae* brief supporting Pfizer's contention that the plaintiff's failure-to-warn claim should be preempted.<sup>51</sup> FDA's brief presented two alternative arguments to support preemption.<sup>52</sup> First, under the theory of conflict preemption, FDA argued that Pfizer would not have been able to comply with both state and federal laws because they conflicted.<sup>53</sup> The Agency noted that on three occasions, FDA had considered and rejected claims that Zoloft and similar other antidepressant drugs cause suicide.<sup>54</sup> Hence, the Agency argued, "FDA, not each state applying its own standards, must approve the warning....[H]ad Pfizer given a warning as to a causal relationship between Zoloft and suicide, FDA would have disapproved that warning" because it "would not have been supported by science."<sup>55</sup>

FDA's second argument presented a much broader theory for preemption. FDA argued that imposing liability based on a failure-to-warn claim would "prevent the accomplishment and execution of the full purposes and objectives of Congress" because the FDCA seeks to ensure a drug's optimal use by requiring that manufacturers disseminate only truthful information.<sup>56</sup> Moreover, the *amicus* brief makes clear that FDA need not have made any prior determination as to a specific warning.<sup>57</sup> This expansive argument can be seen as a move to preserve the agency's authority over drug regulation.<sup>58</sup>

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<sup>49</sup>*Id.* at 1096.

<sup>50</sup>*Id.*

<sup>51</sup>Brief of Amici Curiae FDA, *Motus v. Pfizer, Inc.* Nos. 02-55372 & 02-55498 (9<sup>th</sup> Cir. 2002) (In first paragraph, FDA set forth its objective in filing the brief: It sought "to make clear the basis for federal preemption and the error in the district court's opinion.").

<sup>52</sup>*Id.* at 15-23.

<sup>53</sup>*Id.*

<sup>54</sup>*Id.* at 13.

<sup>55</sup>*Id.* at 17. (The FDA conceded that the district court "properly recognized that state law may not require the manufacturer of a drug to warn of a specific danger that FDA, based on scientific analysis, concludes does not exist." *Id.* at 16. Such a warning would misbrand the drug in violation of the FDCA)

<sup>56</sup>Levy, *supra* note 21 at 506 *citing* Brief of Amici Curiae FDA, at 15-23, *Motus* (Nos. 02- 55372 & 02- 55498).

<sup>57</sup>*Id.*

<sup>58</sup>*Id.*

Although the court in *Motus* refused to find preemption of the failure-to-warn claim, two other pharmaceutical drug cases against Pfizer relied on the Agency’s *amicus curiae* brief in *Motus* to find preemption in failure-to-warn claims.<sup>59</sup> Both *Needleman v. Pfizer, Inc.* and *Dusek v. Pfizer, Inc.* involved plaintiffs who committed suicide while taking Zolof. <sup>60</sup> In each instance, the courts relied on the conflict preemption arguments presented in the *Motus* brief to find for the defendant.<sup>61</sup>

*Needleman* and *Dusek* notwithstanding, the majority of courts have not accepted the FDA’s position on preemption in prescription drug cases.<sup>62</sup> In cases decided subsequent to *Needleman* and *Dusek*, other federal district courts have reached the opposite result. In *Cartwright v. Pfizer*, the plaintiff also argued that Zolof was the cause of her decedent’s suicide.<sup>63</sup> In holding for the plaintiff, the court found that FDA could have enacted a regulation that preempted state law claims but that it had chosen not to.<sup>64</sup> Significantly, the court found that:

Congress and the FDA has [sic] chosen not to include an express preemption clause in the statutes and regulations for prescription drugs. Clearly, Congress knows how to enact FDA legislation that contains a preemption clause. Thus, the absence of any such clause with respect to prescription drugs demonstrates an implied intent not to preempt cases, such as this. <sup>65</sup>

<sup>59</sup>*Needleman v. Pfizer, Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004); *Dusek v. Pfizer Inc.*, 2004 WL 2191804 (S.D. Tex. Feb 20, 1994).

<sup>60</sup>In *Needleman*, shortly after beginning Zolof therapy, plaintiff’s decedent committed suicide. As the Court in *Dusek* observed, the plaintiffs’ failure-to-warn claims in *Needleman* and *Dusek* were indistinguishable. *Needleman*, 2004 WL 1773697 at 5.

<sup>61</sup>*Needleman*, 2004 WL 1773697; *Dusek*, 2004 WL 2191804. Notably, both of these cases were decided *before* the Third Circuit’s decision in *Horn v. Thoratech Corp.*, 376 F.3d 163 (3d Cir. 2004). *Horn* was a case filed under the MDA regarding a heart pump implant that allegedly caused the death of a patient when a suture wore out. The Third Circuit found that the plaintiff’s claims of design defect, strict liability, negligence, and failure-to-warn state tort claims were preempted by the MDA. In its holding the Third Circuit gave substantial weight to the FDA’s *amicus curiae* brief which argued that the § 360k(a) of the MDA preempted state common law claims because they would impose a requirement “different from” or “in addition to” federal requirements imposed by FDA regulations. Brief of Amici Curiae FDA, *Horn v. Thoratech*, No. 02-4597 (3d. Cir. 2004). Even though *Horn* was decided under the MDA, it is important because court decisions decided after this decision indicate a preemptive trend that has evolved from the FDA’s influential *amici curiae*. Levy, *supra* note 21 at 501 (discussing cases that indicate a preemption trend in the courts under the MDA).

<sup>62</sup>ALI-ABA, *supra* note 42 at 387.

<sup>63</sup>369 F. Supp. 2d 876, 881 (E.D. Tex. 2005).

<sup>64</sup>*Id.* at 883, *citing Hillsborough* 471 U.S. at 721. See ALI-ABA, *supra* note 42 at n.210 (noting that in reaching its holding, the *Cartwright* court relied heavily on the decisions of several other federal courts that found that state law failure-to-warn claims are not preempted by the FDCA or FDA regulations). See also *Hurley v. Lederlee Labs.*, 862 F.2d 1173 (5t h Cir. 1987); *Motus*, 127 F.Supp at 1985; *Osburn v. Anchor Labs.* 825 F.2d 908 (5t h Cir. 1987).

Accordingly, the court found that state law failure-to-warn claims do not conflict with federal labeling requirements for prescription drugs.<sup>66</sup> The court concluded that the federal requirements set minimum standards and states are free to impose stricter labeling and warning requirements, as long as the warnings are not false or misleading.<sup>67</sup> In *Zikis v. Pfizer*, which was decided just after the *Cartwright* holding, a district court in Illinois reached the same conclusion, holding that the plaintiff's claims were not preempted by federal law.<sup>68</sup> In rejecting Pfizer's preemption argument, the court also dismissed Pfizer's reliance on "... an Amicus brief filed by the United States Government in another case... [which] contains nothing more than [sic] legal argument by counsel."<sup>69</sup> These two cases are examples of a number of holdings that dismiss drug manufacturers' reliance on the FDA's *Motus* brief.<sup>70</sup>

Although FDA has filed *amicus curiae* briefs in a number of important cases, the Agency's position has met with mixed success in court decisions. By including the preemption provision in the preamble to the revised labeling rule, FDA hoped to eliminate the need to file *amicus curiae* briefs as well as to strengthen its position on the issue.<sup>71</sup>

#### IV.

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<sup>66</sup>*Id.*

<sup>67</sup>*Id.* at 885-886. The judge slapped down Pfizer's conflict preemption arguments saying "...it would be inconceivable to argue that an additional warning regarding suicidality would be false or misleading." The judge pointed out that the law allows, even encourages, manufacturers to be proactive when learning of new safety information related to their drug and that [drug] manufacturers, not the FDA, are tasked with the responsibility of taking proactive steps once a manufacturer learns of "reasonable evidence of an association of a serious hazard with a drug." *Id.* But see 71 Fed. Reg. at 3934. (In the revised labeling rule, FDA specifically rejects this contention, calling such a view a "misunderstanding of the act.").

<sup>68</sup>2005 WL 1126909 (N.D. Ill. May 09, 2005).

<sup>69</sup>ALI-ABA, *supra* note 42 at 388, *quoting* *Zikis*, WL 1126909 at 3.

<sup>70</sup>*See, e.g.*, One state court judge in California, ordered the FDA brief stricken from the record, calling it "hearsay and irrelevant." *Szybinski v. Pfizer*, No. YC 047439 (Cal., Los Angeles County Super. Ct. filed Sept. 8, 2003). In a case pending in Minnesota, the judge rejected Pfizer's arguments, stating that it "declines to treat statements from a single FDA legal brief as declarations afforded the preemptive force of law." The judge also called Pfizer's arguments "perverse" and a "public policy argument gone awry." *Witczak v. Pfizer, Inc.* 377 F. Supp. 2d 726, 730 (D.C. Minn., 2005).

<sup>71</sup>FDA Week, *supra* note 35 (quoting FDA Chief Counsel Sheldon Bradshaw as stating that "the agency cannot become involved in every state product liability lawsuit [alleging failure-to-warn]. [FDA] is using the preamble to make it easier for drug companies to remind the courts of FDA's position on the matter.").

## Initial Reactions to the Preemption Provision Contained in the Preamble to the new Drug Labeling Rule

FDA's decision to include a preemption provision in the preamble to the new rule took lawyers on both sides of the bar by surprise because it was not included in the proposed rule as published for comment. Critics characterize the preemption language as an attempt by the Bush Administration to shield drug companies from liability,<sup>72</sup> while those who favor the rule applaud it as a step in the right direction. Although the preamble has caused quite a stir, it is unclear if it will make a difference with courts because the preemption language is located in the preamble and not in the body of the rule. According to the Washington Post, the FDA recognizes that the regulation's preamble "does not have the weight of law or formal regulation, [but] they hope state judges will accept their position."<sup>73</sup>

A.

### Criticisms of Including A Preemption Provision in the Revised Drug Labeling Rule

In the revised labeling rule's discussion of preemption, FDA makes clear that *at least* six different types of state law tort claims are preempted. This sweeping approach has drawn concern from the NSCL, which views the action as a usurpation of Congressional and state prerogatives.<sup>74</sup> NCSL complained "[t]hey curtail state creativity and state authority, and they often seek uniformity when uniformity is not necessarily the most effective means for resolving issues."<sup>75</sup> Opponents of federal preemption in the public health arena are upset with the manner in which FDA inserted the preemption provision in the regulation. Moreover, they

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<sup>72</sup>Representative Maurice D. Hinchey, Democrat of New York, said that the liability provisions of the new rule showed that the drug agency "has once again gone to bat for the drug industry." Harris "New Drug Label Rule," *supra* note 28.

<sup>73</sup>Marc Kaufman "FDA Tries to Limit Drug Suits in State Courts: Agency's Federal Preemption Policy included in Labeling Guidelines for Medications" Washington Post (Jan. 19, 2006) at <http://www.washingtonpost.com/wp-dyn/content/article/2006/01/18/AR2006011802320.html>

<sup>74</sup>State and Local Government Law Professors Blog, "FDA Final Rule: Prescription Drug Labeling" (Jan. 30, 2006) at [http://lawprofessors.typepad.com/statelocal/2006/01/fda\\_final\\_rule\\_.html](http://lawprofessors.typepad.com/statelocal/2006/01/fda_final_rule_.html).

<sup>75</sup>National Conference of State Legislatures ("NSCL"), "Preemption Monitor" Vol. II, Issue I (Jan. 23, 2006).



say that FDA is not sufficiently equipped to protect the public and that litigation helps to fill in regulatory gaps.<sup>76</sup>

Critics of FDA’s preemption position take umbrage with the manner by which FDA inserted the relevant language into the labeling rule. Senator Edward Kennedy lashed out at the proposal saying “[i]t’s a typical abuse by the Bush Administration – take a regulation to improve the information that doctors and patients receive about prescription drugs and turn it into a protection against liability for the drug industry.”<sup>77</sup> A strongly worded press release by the NCSL echoed Senator Kennedy’s statement, accusing FDA of “attempting a back-door approach to preempt state prescription drug product liability laws despite Congress and the courts’ refusal to grant them such power.”<sup>78</sup> Various stakeholders argue that the Agency should allow for another public comment period over the dramatically different language in the preamble. In a letter written to Michael Leavitt, the Secretary of Health and Human Services, Senator Kennedy and Senator Dodd argued, “[a]t the very least, such a drastic reversal of policy with such far-reaching implications should be subject to public consideration and an opportunity for comment on whether the agency has the legal authority to preempt state requirements.”<sup>79</sup>

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<sup>76</sup>An important non-preemption argument against the revised labeling rule is that major changes to drug labels have done little in the past to stop dangerous prescribing habits by physicians. Public Citizen: Protecting Health, Safety & Democracy, National Non-Profit Public Interest Organization “FDA’s Drug Label Rule Fails to Guarantee Patients Receive Necessary Information,” at <http://www.citizen.org/pressroom/release.cfm?ID=2114>. Moreover, the rule does not address the information sheets routinely provided to patients by pharmacists. Rather, doctors will receive improved information while patients will continue to receive information leaflets whose content is lightly regulated and often fail to include important drug warnings. Dr. Sidney Wolfe, director of Public Citizen’s Health Research Group notes “The FDA’s own study has shown that the content of unregulated leaflets gets a failing grade (average 50 out of 100) in conveying the most important information to patients. . . . It is time to end the double standard where doctors and other health professionals are informed by FDA-approved labeling, but patients are treated like second-class citizens, receiving whatever the out-of-control purveyors of patient information leaflets choose to dispense.” *Id.* See also Harris “New Drug Label Rule,” *supra* note 28.

<sup>77</sup>Letter from Senator Kenney & Senator Dodd to Secretary of Health and Human Services Michael Leavitt (Feb. 23, 2006) (Urging him to stop the preemption provision in the FDA drug labeling regulation because it undermines State consumer protection laws).

<sup>78</sup>**NCSL Press Release, “Proposed FDA Rule Preempts State Product Liability Laws: *Back-door approach seeks powers denied by Congress and the courts*”** (Jan. 13, 2006).

<sup>79</sup>Letter from Sens. Kenney & Dodd, *supra* note 76; see also NCSL press release *supra* note 77 (State Sen. Steven Rauschenberger, R-Elgin, the President of the National Conference of State Legislatures, has said, “It is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide.” Rauschenberger wants the language withdrawn or the labeling rule republished to allow public comment on the controversial provisions).

Consumer rights advocates and other industry watchers see FDA's recent preemption push as an example of the amount of influence big drug companies such as Merck and Pfizer are able to exert on the rulemaking process. Ken Suggs, President of the Association of Trial Lawyers of America ("ATLA") declared:

The fact that the drug industry can get the FDA to rewrite the rules so that CEOs can escape accountability for putting dangerous and deadly drugs on the market is the scariest example yet of how much control these big corporations have over our political process.... an FDA that is beholden to the drug companies it is supposed to regulate – eliminating the rights of individuals to hold negligent drug companies accountable only puts patients at greater risk.<sup>80</sup>

To those who have long condemned the Agency's "coziness" with the drug industry, the preemption language is yet another illustration of FDA compromising public health and safety to pander to the drug companies because they are the source of much of the Agency's budget.<sup>81</sup> Critics of the Agency note that in the past few years, FDA has decreased its budget for independently testing the effects of drugs that are already out on the market.<sup>82</sup> They say that this creates a greater reliance by FDA upon the big drug companies to report problems and that this dependence has worn away at the Agency's willingness to confront drug makers—leaving patients increasingly more vulnerable.<sup>83</sup> FDA's push to preempt state tort claims could

*Id.*

<sup>81</sup>Gardiner Harris "At F.D.A., Strong Drug Ties and Less Monitoring" The New York Times (Dec. 6, 2004) [hereinafter "Strong Ties"]. Citing a financial pact reached in 1992 between drug industry and the government designed to accelerate the approval of new drug applications. "The companies promised to contribute millions in user fees to fund the reviews, and in turn the government agreed to maintain its spending on reviews." The article goes on to note that "[d]ozens of former and current F.D.A. officials, outside scientists and advocates for patients say the agency's efforts to monitor the ill effects of drugs that are on the market are a shadow of what they should be because the White House and Congress forced a marriage between the agency and industry years ago for the rich dowry that industry offered. Under the 1992 agreement, the industry promised to give the agency millions - in the 2003 fiscal year, \$200 million - but only if the agency spent a specified level of money on new drug approvals." *Id.*

<sup>82</sup>*Id.* But see, In fact, challenging the assertion that drug fast-tracking has resulted in the approval of new and potentially dangerous medicines, a Harvard-Michigan study found that the millions of dollars paid in user fees to the FDA by drug companies hasn't sped the approval of new drugs any more than federal funding increases did in the past. "'Approval Times For New Drugs: Does The Source Of Funding For FDA Staff Matter?," with Michael Chernen, A. Mark Fendrick, and Dean Smith? *Health Affairs* (Web Exclusive) December 17, 2003, W3-618-624. (The authors say the findings cast doubt on claims that PDUFA benefited firms that are more powerful disproportionately, or that the user fees directly promote industry influence on the drug approval process. The report also found no evidence that industry funding of fast-track approvals prejudices the process in favor of drug companies.). *Id.* See also, Harris "Strong Ties," *supra* note 80 (disputing that faster drug approval times have made FDA's review process sloppy).

<sup>83</sup>*Id.* See also, David C. Vladeck, "Symposium: Federal Preemption of State Tort Law: The Problem of Medical Drugs" 33 Pepp. L. Rev. 95. ("FDA's ability to single-handedly regulate the market does not match its rhetoric. Daily front page stories....raise serious questions about the ability of the FDA approval process to pro-

make this vulnerability even more pronounced.

Opponents of the labeling rule's preemption language point out that FDA's inadequacy in safeguarding consumer protection reinforces the importance of ensuring manufacturer accountability to consumers through tort law protection.<sup>84</sup> Critics point out that after approving a drug for market, FDA cannot require a drug company to study further benefits and risks.<sup>85</sup> More importantly, FDA does not have the authority to require a company to change the label short of initiating a lengthy court proceeding or withdrawing the drug from the market.<sup>86</sup> In practice, the Agency's inability to require immediate changes in a label means that FDA must negotiate with drug manufacturers to effect changes in the drug label.<sup>87</sup> There are many examples where a manufacturer has refused FDA's request to add important risk information to the label for many months.<sup>88</sup> One of the more high-profile examples of this is the litigation faced by Merck & Co. over its withdrawn painkiller Vioxx. The FDA approved Vioxx in May 1999 but did not document safety issues worthy of a ban until nearly five years later.<sup>89</sup> In the Vioxx case, it took more than 18 months for Merck to add new information about cardiac risks to the label of Vioxx.<sup>90</sup>

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vide adequate assurance of safety by itself."); *see generally*, William M. Janssen & Royce Smith "FDA's Independent Drug Safety Board: The Quest to Restore Confidence in FDA's Stamp of Approval" 21 No. 4 ANPHARLR 11 (May 1999).

<sup>84</sup>MacGillivray v. Lederlee Lab., 667 F. Supp. 743, 745 (D.C.N.M. 1987) (stating that tort law actions can induce drug manufacturers to develop, market, and promote safer products, for the benefit of public health); Graham v. Wyeth Lab. 666 F.Supp. 1483, 1493 (D.C. Kan. 1987) (noting that state tort suits against vaccine manufacturers are consistent with the goal of maximizing national health care. Note that finding preemption of all state law liability claims effectively prevents the use of tort law as a means of consumer protections.

<sup>85</sup>Letter from Sens. Kenney & Dodd, *supra* note 76

<sup>86</sup>*Id.*

<sup>87</sup>*Id.*

<sup>88</sup>*Id.* (noting that the manufacturers often water down the requested language).

<sup>89</sup>Anna Wilde Matthews, "FDA Plan Would Aid Drug Makers in Liability Suits" The Wall Street Journal (Jan. 14, 2006) (Merck pulled the hugely popular drug from the market in 2004 following a study that linked the drug to an increased risk of heart attacks and strokes in patients taking it for 18 months or longer).

<sup>90</sup>*Id.* *See also*, Lisa Brennan "New FDA Rule's Preamble Stirs Up Bar on Both Sides" (Feb.1, 2006) at [www.law.com](http://www.law.com) (quoting plaintiffs lawyer Christopher Placitella as saying "The FDA has [only] two reviewers who review all promotional materials put out by drug companies. This preemption policy is an attempt to give pharmaceutical companies absolution so long as the package insert is approved.")

Although it is not yet clear how much deference courts will give to the Agency’s latest assertion of preemption, without state product liability laws, critics fear that drug companies could escape responsibility for injuries and deaths.<sup>91</sup> Several commentators and some courts have noted that tort regimes are an important way to fill in regulatory gaps and to encourage drug manufacturers to be accountable to the public.<sup>92</sup> According to this argument, “the vitality of tort law in pharmaceutical products liability jurisprudence encourages manufacturers to develop safer products and to include more accurate warnings, consistent with the FDCA’s overall goal of consumer protections.”<sup>93</sup> Therefore, if courts follow the FDA’s preemption position, drug manufacturers will have only weak financial incentives to warn patients of harmful effects of drugs already on the market.<sup>94</sup> Preemption opponents also cite the powerful incentives that tort liability provides to drug manufacturers to ensure consumer safety and cite preemption defenses as efforts by industry to shed an important source of market discipline that regulation alone cannot provide.<sup>95</sup> Therefore, the alleged failure of FDA to monitor effectively drug safety paired with the potential inability of consumers to file liability claims could be devastating.<sup>96</sup>

## B.

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<sup>91</sup>Kaufman, *supra* note 72.

<sup>92</sup>Rieders, *supra* note 9 at 1177, 1178 *citing* MacGillivray 667 F.Supp; Barbara L. Atwell, Products Liability and Pre-emption: A Judicial Framework, 39 Buff. L. Rev. 181 (1991) (“Permitting tort claims... clearly furthers the goal of keeping the public informed by giving manufacturers and incentive to be as direct and forthright in their warnings as possible.”). *See also*, Reiders, *supra* note 9 at n.104 quoting Marilyn P. Westerfield, Federal Preemption and the FDA: What does Congress Want?, 58 U. Cin. L. Rev. 263, 281 (1989) (“The FDA is ...an improper forum for reviewing injuries to plaintiffs and providing appropriate remedies. Congress and the courts have long recognized that fact, which is why redress for injuries is properly left to the courts.”). *But see*, David Geiger & Mark Rosen, Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical (arguing that in light of the FDA approval process, tort law recoveries conflicts with ensuring affordability and availability of reasonably safe pharmaceuticals.)

<sup>93</sup>Vladeck, *supra* note 82 at 97 (“But too often there are regulatory gaps that jeopardize public safety. Since the founding of our Republic, tort liability has filled those gaps by providing compensation to those who are injured and by deterring unwarranted risk-taking. But the safety net of tort liability is under assault by aggressive, and often successful, assertions of federal preemption.”).

<sup>94</sup>Vladeck, *supra* note 82 at 130 (making parallel argument in the context of MDA litigation).

<sup>95</sup>*Id.* at 101.

<sup>96</sup>“This is a dangerous situation, made worse by the FDA’s poor record of approving harmful drugs based on limited, and even fraudulent, clinical trials performed by the drug companies.” Consumer Affairs Press Release “FDA’s New Drug Label Rule Blasted” (Jan. 19, 2006).

## Arguments in Favor of Including A Preemption Provision in the Revised Drug Labeling Rule

When examining the motivations underlying policy decisions made by FDA, it is important to recognize that the Agency labors under skewed incentives: keeping good drugs off the market harms people (but rarely generates public outcry) while letting dangerous drugs on the market can harm or kill people resulting “in public scorn and congressional investigations.”<sup>97</sup> Those in favor of a preemption provision in the labeling rule argue that such a provision “will not make the FDA less risk-averse than it already is... the heat’s still on even if the pre-emption barrier is rock solid.”<sup>98</sup> In tune with FDA’s aversion to risk and its mission to protect the public health and safety, the Agency hopes that limiting drug manufacturer’s liability in state courts will lower manufacturing costs and increase drug availability; increase safety by making important information more accessible; and maintain the Agency’s position as the supreme authority in public health and safety.

The preemption provision marks a continuation in the direction the FDA has been heading under the current Presidential Administration. In recent years, FDA has intervened in a number of high-profile state liability cases against drug and medical device manufacturers with *amicus curiae* briefs supporting the drug companies. Therefore, FDA officials say that including the preemption policy statement in the preamble to the revised labeling rule is just another way to make the same points on a broad and general basis.<sup>99</sup> Proponents of the preemption provision believe that pharmaceutical warning labels contain little useful information for consumers;<sup>100</sup> rather, labels attempt to over-warn of every potential side effect so as to protect manufacturers from being sued. It is hoped that the new labeling provisions will provide better

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<sup>97</sup>Richard Epstein, “A Welcome Revolution: Reducing Delays to Market” *The National Law Journal* (Feb. 6, 2006).

<sup>98</sup>*Id.*

<sup>99</sup>Kaufman, *supra* note 72 *quoting* Scott Gottlieb, M.D., FDA’s Deputy Commissioner for Medical and Scientific Affairs.

<sup>100</sup>“The labels had become cluttered over time with a lot of information that wasn’t necessarily directly pertinent to the patient and the physician.” Heidi Belden, Pharm D., “FDA’s New Rx Label Rule May Limit Lawsuits” *Drug topics: The Online Newsmagazine for Pharmacists* (Feb. 20, 2006) at <http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=307589> *quoting* Gottlieb.

information to consumers and prevent hyperactive litigation.<sup>101</sup>

Although the preemption language in the preamble has met with some resistance, FDA maintains that its actions will provide manufacturers with much needed uniform labeling requirements.<sup>102</sup> The benefit to such uniformity is that the public will have greater access to “timely, innovative, and affordable healthcare.”<sup>103</sup> Today, developers of new drugs must set aside billions of dollars in anticipation of the potentially unlimited risk of mass tort lawsuits.<sup>104</sup> This is money redirected from potentially valuable research activities.<sup>105</sup> Even worse, healthcare innovation is impeded when manufacturers choose to devote finite research and development resources to creating products they believe will not be associated with high-stakes liability costs.<sup>106</sup> By inserting the preemption language into the new labeling rule, FDA seeks to achieve lower costs and wider availability of safe drugs.<sup>107</sup>

Proponents of expanding federal preemption in the public health context cite consumer safety as their chief concern:

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<sup>101</sup>John Calfee, “Striking a Balance: Drug Labeling and the FDA” American Enterprise Institute for Public Policy Research (Feb. 10, 2006).

<sup>102</sup>Geiger & Rosen, *supra* note 91 at 420 (arguing that in light of the FDA approval process, tort law recoveries conflicts with ensuring affordability and availability of reasonably safe pharmaceuticals.) *See also* 71 Fed. Reg. at 3935 (after FDA issued the NPRM, manufacturers conveyed their concerns that thinning out the package insert and highlighting only the most important warnings, instead of presenting a comprehensive list of every possible effect, would open them up to legal action under state tort law for failing to warn. FDA agreed that the new streamlined format would make drug manufacturers more vulnerable to lawsuits because it removes some of the “legal disclaimers” previously contained in the package inserts).

<sup>103</sup>Peter J. Pitts, “Unhealthy Litigation” The Washington Times at [www.washingtontimes.com](http://www.washingtontimes.com) (criticizing products liability cases for impairing public access to beneficial drugs. E.g., Benedictine litigation was later proven not to cause birth defects yet by 1983 costs of lawsuits was so great that the manufacturer withdrew the product from the market).

<sup>104</sup>*Id.* (“The lack of innovation in the areas of vaccines, contraceptive products, and “orphan drugs,” or drugs for serious and life-threatening diseases that affect small segments of the population... only begins to illustrate the point that more liability results in less innovation.”)

<sup>105</sup>*Id.*

<sup>106</sup>*Id.*

<sup>107</sup>71 Fed. Reg. at 3935. Law Professors Blog, *supra* note 74 ( “State law requirements can undermine safe and effective use’ of drugs, by creating pressure on drug manufacturers to provide information on ‘speculative risks’ and accordingly to ‘limit physician appreciation of potentially far more significant contraindications and side effects.’”). *See generally*, Geiger & Rosen *supra* note 92.

Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.<sup>108</sup>

FDA goes on to provide other examples of how “state law requirements can undermine safe and effective use.”<sup>109</sup> “Liability concerns create pressure on manufacturers to expand labeling warnings to include speculative risks and lead to labeling that does not accurately portray a product’s risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use.”<sup>110</sup> Moreover, the agency asserts that product liability litigation “creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically requires [which leads to] defensive labeling.”<sup>111</sup>

Significantly, the preemption provision seeks to guard FDA’s position of authority on health and safety matters.<sup>112</sup> Defenders of the FDA’s preemption language have argued that it simply articulates a stance that is implicit in federal law.<sup>113</sup> . “You want the FDA to have the last word if you believe in the FDA’s expertise,” said Daniel Troy, the former FDA chief counsel who filed several of the Agency’s *amicus curiae*

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<sup>109</sup>*Id.*

<sup>110</sup>*Id.* (See, e.g., *Dowhal v. SmithKline Beecham Consumer Healthcare*, 2002 Cal. App. LEXIS 4384 (Cal. Ct. App. 2002) (allowing to proceed a lawsuit involving a California State law requiring warnings in the labeling of nicotine replacement therapy products that FDA had specifically found would misbrand the products under the act), *reversed*, 2004 Cal. LEXIS 3040 (Cal. April 15, 2004).)

<sup>111</sup>71 Fed. Reg. at 3935

<sup>112</sup>*Id.* (“State law actions also threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA—sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required.”).

<sup>113</sup>Matthews, *supra* note 88.

briefs.<sup>114</sup> Scott Gottlieb, M.D., FDA’s deputy commissioner for medical and scientific affairs, argued that companies whose drugs are evaluated and approved by the FDA should not be second-guessed by state courts that do not have the same scientific knowledge.<sup>115</sup> If state lawmakers and courts can question FDA’s determinations, it could subject drug manufacturers to a wide array of rules in each state, which would undermine the decisions of the government’s most qualified experts

V.

#### Practical effects of the Preemption Language on Court Determinations

The ultimate legal weight of FDA’s preemption policy statement on product liability cases remains to be seen. Although the *Chevron* doctrine requires courts to give substantial deference to an agency’s pronouncements regarding the scope and effect of its implementing legislation and regulation, it is unclear what level of deference will be accorded in this situation where the FDA’s view is set forth in the Preamble to a rule—not a codified regulation.<sup>116</sup> Although statements contained in the preamble constitute advisory opinions and represent the formal position of FDA on a matter,<sup>117</sup> advisory opinions are not legal requirements.<sup>118</sup> However, as a practical matter, the preamble should be afforded greater deference by courts than the FDA’s *amicus curiae* briefs.<sup>119</sup>

While there is no guarantee that courts will accept the FDA’s view on preemption, the Preamble provides

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<sup>114</sup>*Id.*

<sup>115</sup>Belden, *supra* note 99.

<sup>116</sup>*Chevron* 467 U.S. 837 (*Chevron* only requires courts to give agency pronouncements “substantial deference”; it does not absolutely bind courts to an agency’s views). *Cf.* *Medtronic*, 518 U.S. at 500 (deferring to FDA interpretive regulations concerning scope of express preemption).

<sup>117</sup>21 C.F.R. § 10.85(d)(1) & (e).

<sup>118</sup>21 C.F.R. § 10.85(k).

<sup>119</sup>*U.S. v. Mead Corp.*, 553 U.S. 218, 228 (2001) (formal statements of an agency’s policy are more persuasive than litigation briefs).



manufacturers with a formal statement by FDA that can be used in with courts and juries. Nevertheless, plaintiffs' lawyers will likely argue for a narrow interpretation of FDA's position or to attempt to persuade courts to disregard FDA's views altogether. A former general counsel for the Agency says that the preemption language in the labeling rule "...will make it impossible to file liability claims."<sup>120</sup> Interestingly, another former FDA counsel says the preamble is nothing more than a nonbinding advisory opinion. "It won't be persuasive to the courts."<sup>121</sup>

Industry watchers also have conflicting views about the Preamble's influence. Brian Wolfman, director of the Public Citizen Litigation Group and an expert on preemption law expressed his strong opposition to the preemption language noting "[u]ltimately, we are confident that the courts will not defer to the FDA's opinion on preemption, which is not based on any authority given to the FDA by Congress"<sup>122</sup> Proponents of the new rule on the other hand think that this is a step in the right direction. Richard Epstein, a well-known law professor and prolific author, recently wrote that the preemption provision is likely to survive any judicial challenges that seek to brand it as an abuse of administrative discretion.<sup>123</sup> Epstein notes "[t]he FDA has broad administration powers, and the trend in recent Supreme Court pre-emption cases gives extensive deference to the choices of agencies in their core area of expertise. This proposed reform need not rest, however, on the crutch of judicial deference because it is fully defensible on the merits."<sup>124</sup>

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<sup>120</sup>Harris "New Drug Label Rule," *supra* note 28, *quoting* Peter Barton Hutt, former Chief Counsel of FDA.

<sup>121</sup>Brennan, *supra* note 89, *quoting* Former FDA Chief Counsel James O'Reilly. *See also* Matthews, *supra* note 89 (This debate rages inside the FDA as well. It has been said that inclusion of the preemption language in the revised rule has caused tension between career FDA officials and Bush administration appointees. "Some FDA career staffers have argued internally that it isn't relevant to the rule's focus on drug-labeling reform, and may draw controversy to an important regulatory improvement that isn't itself politically divisive. In addition, career officials believe debate over the matter has helped delay the labeling change from taking effect.").

<sup>122</sup>Public Citizen, *supra* note 45. "Only time will tell how much influence the preemption language will have over product liability cases against drug manufacturers....[In the meantime, however, drug companies] will be emboldened by this preemption statement, and use it to complicate injury cases and deter victims from seeking justice in the courts." *Id.*

<sup>123</sup>Epstein, *supra* note 96.

<sup>124</sup>*Id.* (Epstein later asserts that "[t]he tort system, in general, works best with automobile accidents, where clear rules of the road and physical evidence – who hit whom – resolve disputes quickly. But the more sprawling the litigation, the less the reliability, and the smaller the chance that the law can serve its acknowledged twin goals of compensation and deterrence.") *Id.* *See also*, Sidley Austin LLP memo "FDA Stakes Out Pro-Preemption Position in Physician Labeling Rule, 2006 WLNR 1428318 (Jan. 24, 2006)" (noting that this is not the first time FDA has expressed preemptive intent in a preamble).

Although the influence of the provision will remain unclear until courts have the opportunity to rule on the new rule, it is likely that the courts will give deference to the preemption language contained in the preamble.<sup>125</sup> Partly in response to criticisms that FDA's preemption position was not expressed in regulations<sup>126</sup> the Agency included a formal preemption policy statement in the labeling rule. Given the Agency's unique expertise and knowledge in the regulation of pharmaceuticals, courts will probably find these statements persuasive.

## VI.

### Conclusion

Like most federal agencies, FDA has historically resisted becoming involved in private products liability litigation<sup>127</sup> and some commentators have argued that the Agency's pro-preemption push is ill timed.<sup>128</sup> Notwithstanding the timing, FDA's reform efforts should be allowed to continue. Court recognition of FDA preemption can actually can avoid retardation of innovation by affording a measure of financial security to manufacturers. Such security encourages growth, development, and advancements.<sup>129</sup> Allowing for manufacturer liability for drugs that have already been approved may make companies less likely to market approved products with life-saving benefits. Moreover, companies may remove beneficial drugs from the market if their fear large losses from possible tort liability. Establishing a sound public health policy requires significant knowledge, expertise, and experience. Allowing the Agency to determine which state laws should

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<sup>125</sup>See, e.g., Sidley Memo, *supra* note 124; Covington & Burling LLP Memo, "FDA Final Rule on Prescription Drug Labeling & Statement on Preemption of State Product Liability Laws" (Jan. 27, 2006) at [www.cov.com](http://www.cov.com); and Dechert Memo, *supra* note 23

<sup>126</sup>cite case (cartwright maybe?)

<sup>127</sup>Vladeck, *supra* note 82 *citing* Margaret H. Clune, "Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine (arguing that Bush Administration has pursued tort reform through legal means largely hidden from public view rather than by asking Congress to change the laws).

<sup>128</sup>*Id.* at 126 (arguing that FDA is pushing for preemption in a time of regulatory failure given the well-publicized MDA cases where FDA has been unable guarantee public safety).

<sup>129</sup>Pitts, *supra* note 103; Levy, *supra* note 21 at 508.

be preempted embraces the very mission of the Agency, which is to protect the public's health.